PTO/SB/21 (09-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE nder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/679.038 TRANSMITTAL Filing Date October 2, 2003 First Named Inventor **FORM** MIKSZTA et al. Art Unit 1648 **Examiner Name** TBD (to be used for all correspondence after initial filing) Attorney Docket Number P-5331P1P1 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Fee Transmittal Form Drawing(s) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a **Proprietary Information** After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Identify Terminal Disclaimer **Extension of Time Request** below): Request for Refund **Express Abandonment Request** CD, Number of CD(s) Information Disclosure Statement Landscape Table on CD Certified Copy of Priority Remarks Document(s) Supplemental IDS Reply to Missing Parts/ Incomplete Application PTO/SB08A and 08B (3 pages) Reply to Missing Parts under 37 CFR 1.52 or 1.53 Copies of References and Search Report SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name BECTON, DICKINSON AND COMPANY Signature Printed name J. TIMOTHY MEIGS Date Reg. No. 38,241 **CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: Signature Date Typed or printed name

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| App. No.: | 10/679,038 | Confirmation No. 1660 |
|------------------------|------------|--|
| Applicant(s): | | MIKSZTA et al. |
| Filed: | | October 2, 2003 |
| Title: | | INTRADERMAL DELIVERY OF VACCINES AND GENE THERAPEUTIC AGENTS VIA MICROANNULA |
| Art Unit: | | 1648 |
| Examiner: TBD | | |
| Docket No.: P-5331P1P1 | | P-5331P1P1 |

Mail Stop: Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 and 1.98, Applicants submit this Supplemental Information Disclosure Statement to bring to the attention of the Examiner, for consideration in connection with the above-referenced patent application, certain documents cited in Supplementary European Search Report for European Application No. EP 02 76 3212, which is a counterpart foreign application.

Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the references listed on the attached form PTO/SB/08A be considered by the Examiner and made of record. Copies of the Supplementary European Search Report and listed references are included. Pursuant to the provisions of MPEP § 609, Applicants request that a copy of the PTO/SB/08A form be initialed as being considered by the Examiner and returned to Applicants with the next official communication.

App. No. 10/679,038 Docket No. P-5331P1P1

This submission should not be construed as an admission that the references cited herein are relevant or material to patentability or constitute "prior art" to the subject patent application.

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. § 1.97(b) before the mailing date of a first Office Action on the merits. No fees are therefore believed to be due. However, if it is determined that a fee is required, the Commissioner is authorized to charge the appropriate fee, or credit any overpayment, to Deposit Account No. 02-1666.

Any questions concerning this application or submission may be directed to Applicants' undersigned attorney at the below-listed telephone number.

Respectfully submitted,

January 5, 2006

J. Timothy Meigs

Attorney for Applicant(s)

Reg. No. 38,241 (919) 597-6276

PTO/SB/08A (07-05) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Inder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 3

| Col | mplete if Known | |
|------------------------|-----------------|---|
| Application Number | 10/679,038 | - |
| Filing Date | October 2, 2003 | |
| First Named Inventor | MIKSZTA et al. | |
| Art Unit | 1648 | |
| Examiner Name | TBD | |
| Attorney Docket Number | P-5331P1P1 | |

| | | | U. S. PATENT D | | |
|-----------------------|--------------|---|--|--|---|
| Examiner Initials* | Cite No.1 | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ^{2 (# known)} US- | | | , iguios Appeai |
| | | 05- | | | |
| | | US- | | | |
| | <u> </u> | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| - | | US- | | | |
| | | US- | | | |

| | | FORE | IGN PATENT DOCU | JMENTS | | |
|--------------------|--------------|---|---------------------|--|---|----|
| Examiner Initials* | Cite No.1 | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | |
| | | Country Code ³ "Number ⁴ "Kind Code ⁵ (if known) | MM-DD-YYYY | | Or Relevant Figures Appear | T⁵ |
| | | EP 1 092 444 A | 04-18-2001 | Becton, Dickinson and Co. | | |
| | | WO 02/02179 A | 01-10-2002 | Becton, Dickinson and Co. | | |
| | | WO 02/32454 A | 04-25-2002 | SmithKline Beecham Bio. | | |
| | | WO 02/067983 A | 09-06-2002 | SmithKline Beecham Bio. | | |
| _ | | WO 02/087494 A | 11-07-2002 | GlaxoSmithKline Bio. | | |
| | | WO 02/083216 A | 10-24-2002 | Becton, Dickinson and Co. | | |

| Examiner | | Date | |
|-----------|--|------------|--|
| Signature | | Considered | |
| | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Approved for use through 07/31/2006. OMB 0851-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Sub | stitute for form 1449/PTO | | Complete if Known | 1 |
|------------------------|----------------------------------|--------------------|---------------------|---|
| | | Application Number | er 10/679,038 | _ |
| INFORMATION DISCLOSURE | | SIDE Filing Date | October 2, 2003 | _ |
| | | First Named inver | ntor MIKSZTA et al. | _ |
| S | TATEMENT BY APPL | | 1648 | _ |
| | (Use as many sheets as necessar) | Examiner Name | TBD | _ |
| Sheet | 2 of 3 | Attorney Docket N | lumber P-5331P1P1 | 7 |

| | 1 | | U. S. PATENT D | OCOMEN 13 | |
|-----------------------|--------------|--|--------------------------------|--|---|
| Examiner Initials* | | Document Number Number-Kind Code ^{2 (# known)} | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | ├ | US- | | | |
| | 1 | 05- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | · | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | - |
| | <u> </u> | US- | | | *** |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | **** | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | 1 | | |

| | | FORE | IGN PATENT DOCL | JMENTS | | |
|-----------------------|--------------|---|---------------------|--|---|----|
| Examiner Initials* | Cite No.1 | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | |
| | | Country Code ³ "Number ⁴ "Kind Code ⁵ (if known) | MM-DD-YYYY | | Or Relevant Figures Appear | Τ° |
| | | WO 02/074336 A | 09-26-2002 | SmithKline Beecham Bio. | | |
| | | | | | | |
| | | | | | | L |
| | | | | | | |
| | | | | <u> </u> | | |
| | | | | | | |

| Examiner | Date | |
|-----------|------------|--|
| Signature | Considered | |
| _ | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the senal number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language

Transation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (07-05)

P-5331P1P1

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/679,038 Filing Date INFORMATION DISCLOSURE October 2, 2003 STATEMENT BY APPLICANT **First Named Inventor** MIKSZTA et al. Art Unit 1648 (Use as many sheets as necessary) **Examiner Name** TBD

Attorney Docket Number

3

Sheet

| | 1 03 | NON PATENT LITERATURE DOCUMENTS | |
|-----------------------|--------------------------|---|---|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T |
| | | DEGANO P. et al., Intradermal DNA Immunization of Mice Against Influenza A Virus Using the Novel PowderJect System, Vaccine, Vol. 16, No. 4, February 1998 pp. 394-398 | |
| | | HAENSLER J. et al., Intradermal DNA Immunization by Using Jet-Injectors in Mice and Monkeys, Vaccine, Vol. 17, No. 7-8, February 1999, pp 628-638 | |
| | | RAZ E. et al., Intrad. Gene Immun. the Possible Role of DNA Uptake in the Induction of Cell. Immunity to Viruses, Proc. Nat. Acad. Sci., Vol. 91, No. 20, Sept. 1994 pp 9519-23 | |
| | | HELLER R. et al., Intradermal Delivery of Interleukin-12 Plasmid DNA by in Vivo Electroporation, DNA and Cell Biology, Vol. 20, No. 1, January 2001 pp 21-26 | |
| | | Supplementary European Search Report for EP 02 76 3212, dated 14 October 2005 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Examiner Date Signature Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.